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INTERNATIONAL PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
NEIL P. FARRARO
WOLF, GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MA 02210

PCT

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference L0532.70034 W000		Date of Mailing (day/month/year) 16 FEB 2005
International application No. PCT/US03/34095		REPLY DUE within 1 months/days from the above date of mailing
International filing date (day/month/year) 24 October 2003 (24.10.2003)	Priority date (day/month/year) 24 October 2002 (24.10.2002)	
International Patent Classification (IPC) or both national classification and IPC IPC(7): G01N 37/00, 33/02, 33/14 and US Cl.: 436/56, 20, 24		
Applicant VERIFICATION TECHNOLOGIES, INC.		

- This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
- This opinion contains indications relating to the following items:

I	<input checked="" type="checkbox"/>	Basis of the opinion
II	<input type="checkbox"/>	Priority
III	<input type="checkbox"/>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	<input type="checkbox"/>	Lack of unity of invention
V	<input checked="" type="checkbox"/>	Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	<input type="checkbox"/>	Certain documents cited
VII	<input type="checkbox"/>	Certain defects in the international application
VIII	<input checked="" type="checkbox"/>	Certain observations on the international application

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FEB 18 2005

Initials
Confirmation
Docketing
04/16/05
03/16/05 NO EXT
02/24/05 - afe
NPF

- The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
- The final date by which the international preliminary examination report must be established according to Rule 69.2 is: **24 February 2005 (24.02.2005)**.

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer <i>[Signature]</i> Yelena G. Gakh, Ph.D. Telephone No. (571) 272-1700
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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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PCT/US03/34095

24 October 2003 (24.10.03)

24 October 2002 (24.10.2002)

International Patent Classification (IPC) or both national classification and IFC

IPC(7): G01N 37/00 14 and 36/56, 20, 24

Applicant

VERIFICATION TECHNOLOGIES, INC.

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

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4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 24 February 2005 (24.02.2005).

Name and mailing address of the IPEA/US

Mail Stop PCT, Attn: IPEA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Yelena G. Gakh, Ph.D.

Telephone No. (571) 272-1700

I. Basis of the opinion**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed
- ☒ the description:
pages 1-23, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the claims:
pages 24-43, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the drawings:
pages none, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

WRITTEN OPINION

International application No.
PCT/US03/34095

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims	<u>Please See Continuation Sheet</u>	YES
	Claims	<u>Please See Continuation Sheet</u>	NO
Inventive Step (IS)	Claims	<u>Please See Continuation Sheet</u>	YES
	Claims	<u>Please See Continuation Sheet</u>	NO
Industrial Applicability (IA)	Claims	<u>Please See Continuation Sheet</u>	YES
	Claims	<u>Please See Continuation Sheet</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-2, 6, 14, 16-21, 24-26, 59-60, 64, 72, 74-79, 82-84 and 88-92 lack novelty under PCT Article 33(2) as being anticipated by Parekh (US 3,615,232).

Parekh discloses "method and reagent for determining total cholesterol in blood serum". "In a method for the determination of total cholesterol in blood serum, plasma or other cell free body fluid the steps of adding a reagent comprising a mixture of ferric acetate $[\text{Fe}(\text{C}_2\text{H}_3\text{O}_2)_3]$ and uranium acetate $[\text{UO}_2(\text{C}_2\text{H}_3\text{O}_2)_3]$ to the fluid whereby the total cholesterol content thereof is solubilized and *those chromogens which interfere with the determination are precipitated and separating the liquid phase containing solubilized cholesterol from the precipitate*. The cholesterol content is then determined quantitatively, preferably colorimetrically, employing as a color-developing reagent a mixture of ferrous sulfate and sulfuric acid" (Abstract). This covers the subject matter of the above claims.

Claims 3-5, 15, 22-23, 30-37, 43-55, 61-63, 73 and 80-81 lack an inventive step under PCT Article 33(3) as being obvious over Parekh in view of Kamuf ("Caramel Color") or Kuntz ("Natural Food Colors"). Parekh does not specifically disclose positively and negatively charged caramel colors, which can be precipitated by the oppositely charged caramel colors in order to detect other colored traces. Kamuf and Kuntz disclose different classes of caramel colors, including positively and negatively charged caramel colors, which precipitate upon adding caramel colors of the opposite charge (Kamuf, page 3, the last paragraph; Kuntz, page 2). It would have been obvious for any person of ordinary skill in the art to apply Parekh's method specifically to beverages containing caramel colors along with other coloring agents, with caramel colors interfering with detecting other coloring agents, e.g. FD&C Blue #1, because Kamuf and Kuntz indicated that one type of caramel colors can be precipitated by an oppositely charged type of caramel colors thus avoiding well-recognized problem of interfering caramel colors with detecting other colored agents (traces).

Claims 7-13, 27-29, 36, 38-42, 56-58, 65-71 and 85-87 lack an inventive step under PCT Article 33(3) as being obvious over Parekh in view of Dechabumphen (World Surfactant Congress). While Parekh does not specifically use MYTAB for precipitating coloring agents, Dechabumphen discloses MYTAB as a precipitating agent for cationic surfactants. It would have been obvious for any routineer in the art to use MYTAB for as a precipitating agent in Parekh's method, since Dechabumphen demonstrated its efficiency as a precipitating agent for cationic surfactants.

----- NEW CITATIONS -----

US 3,615,232 (PAREKH) 26 October 1971 (26.10.1971).

DECHABUMPHEN et al. "Contact angle of surfactant solutions on precipitated surfactant surfaces: II. Effect of surfactant charge, pH, use of surfactant mixtures, and surfactant/counterion ratio", World Surfactants Congress, 5th Firenze, Italy, May 29-June 2, 2000, pp. 844-851

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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 4-5, 7, 33-34, 36, 62-63 and 65 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claims are indefinite for the following reason(s): claims 4-5, 33-34 and 62-63 recite Type I, Type 2 and Type 3 caramel colors without specifically indicating, which caramel colors these might be. There is no unified classification of the caramel colors, and therefore Type 1, 2, 3 are not conventional groups of caramel colors, which renders the claims unclear and indefinite; claims 7, 36 and 65 recite "a cationic or quaternary surfactant or a polymer thereof". While the term "cationic surfactant" is clear and definite, the expressions "quaternary surfactant" and "a polymer thereof" are not.

WRITTEN OPINION

International Application No.
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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 3-5, 15, 22-23, 30-37, 43-55, 61-63, 73, 80-81

The opinion as to Novelty was negative (No) with respect to claims 1-2, 6, 14, 16-21, 24-26, 59-60, 64, 72, 74-79, 82-84, 88-92

The opinion as to Inventive Step was positive (Yes) with respect to claims NONE

The opinion as to Inventive Step was negative (NO) with respect to claims 1-92

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-92

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE